IND-enabling Studies of Wearable Evolve-FSTL1 for Cardiac Regeneration after MI

Grant Award Details

IND-enabling Studies of Wearable Evolve-FSTL1 for Cardiac Regeneration after MI

Grant Type: Therapeutic Translational Research Projects

Grant Number: TRAN1-12907

Project Objective: The conduct of a well prepared pre-IND meeting with the FDA to support development of unglycosylated FSTL1 as a subcutaneoulsy administered, post myocardial infarction therapy to prevent progression to heart failure.

Investigator:

Name:	PILAR RUIZ-LOZANO
Institution:	Regencor, Inc.
Type:	PI

Disease Focus: Heart Disease

Human Stem Cell Use: iPS Cell

Award Value: $3,923,191

Status: Active

Grant Application Details

Application Title: IND-enabling Studies of Wearable Evolve-FSTL1 for Cardiac Regeneration after MI

Public Abstract:

Translational Candidate

The therapeutic candidate is the Regencor's proprietary Cardio-Regenerative Factor (FSTL1.37) formulated in the Wearable Injector Evolve-FSTL1.

Area of Impact

The targeted area of impact is to restore cardiac function and reduce progression to heart failure in patients after myocardial Infarction

Mechanism of Action

FSTL1.37 activates the controlled proliferation of progenitor heart cells within the infact zone. The result of the treatment increases animal survival, reduces the progression to heart failure, substantially reduces cardiac scar size, restores cardiac function to nearly pre-infarct levels, and stimulates the formation of new cardiomyocytes and blood vessels. All these effects are limited exclusively to the infarct zone, and no adverse effects have been detected.

Unmet Medical Need

Heart failure is a growing unmet medical need, with an enormous economic and societal burden worldwide, and remains incurable.Only regenerative therapies address the root cause of cardiac dysfunction and progression to heart failure after myocardial infarction.

Project Objective

Pre-IND dossier for SubQ CardioRegenerative Factor

Major Proposed Activities

- FSTL1.37 production using a cGMP-compliant process
- cGLP-compliant dose efficacy and Toxicity, including Comorbidity
- Variations of effect in race and sex

Statement of Benefit to California:

Heart disease is still the leading cause of death in California, accounting for 23% of all deaths. 62,797 Californians died of heart disease in 2017 compared to 16,355 who died of stroke. California will benefit from the proposed cardio-regenerative therapy by reducing death and disability of its citizens after MI, and by reducing their progression to heart failure, resulting in lower health care costs and preserved productivity for Californians with heart disease.
